REMARKS

The Examiner's final Office Action dated April 19, 2004 has been [illegible]ceived and its contents carefully noted. In response, claim 3 has been amended to correct the dependency from claim 2, which has been canceled, to claim 9 (which was previously original claim 2). Claims 1, 3-9 remain pending and of which claims [illegible] and 9 are independent. The Examiner's indication that claim 9 is allowed is greatly appreciated. In light of the detailed arguments to follow, reconsideration of the current rejections is respectfully requested.

With regard to the Examiner's repeated rejections of:

Claims 1, 3, 4, and 6-8, under 35 U.S.C. §102(b), as being anticipated by U.S. Patent No. 4,984,564 to Yuen,

Claims 1, 3, 4, and 6-8, under 35 U.S.C. §102(b), as being anticipated by U.S. Patent No. 5,634,937 to Mollenauer et al., and

Claims 1 and 3-8, under 35 U.S.C. §102(b), as being anticipated by U.S. Patent No. 5,545,179 to Williamson, IV

the Applicants continue to traverse each of these rejections for the reasons set forth in the Amendment of November 7, 2003 and for the additional reasons set forth below.

Specifically, with regard to the rejection of claims 1, 3, 4, and 6-8, under §102(b), as being anticipated by to Yuen, the Applicants note that the surgical device of claim 1 sets forth the following features:

> ... having:
>
> distal body cavity engagement means (5) for insertion into the incision to locate the device in position;
>
> proximal fixing means (6) for attaching the device to a patient's skin;
>
> a sleeve (4) connected between the body cavity engagement means (5) and the fixing means defining an access port; and
>
> characterized in that the device includes sealing means (10, 12), operating on the sleeve (4) to prevent substantial leakage of gas from the body cavity (2) on inflation when in an inoperative position and formed to mould to a substantial portion of a surgeon's hand or surgical instrument on insertion in an operating position, the sealing means being provided by an inflatable first seal (10) for engaging and retracting the incision and a

second **inflatable** seal (12) for sealing the lumen of the tube or sleeve bore. (Emphasis added)

With regard to the above highlighted limitations, the Applicants note that the Examiner must give the above limitations the broadest reasonable interpretation consistent with the specification, as required by MPEP Chapter 2111, and in that interpretation the claim terminology must be given their plain, i.e., ordinary and customary, meaning understood by those of ordinary skill in the prior art, see MPEP Chapter 2111 (II) (Rev. 2 May 2004).

It is asserted that the Examiner has utterly failed to comply with these requirements by the very insistence that the Yuen patent teaches the above highlight claim features of "a sleeve...sealing means (10, 12), operating on the sleeve (4) to prevent substantial leakage of gas from the body cavity...the sealing means being provided by an inflatable first seal (10) for engaging and retracting the incision and a second **inflatable** seal (12)".

That is, the examiner states in the Office Action that:

> Yuen discloses a device for use in minimally invasive surgery using an inflated body cavity accessible to a surgeon through an access port, defined by the device, surrounding an incision in a patient's body (see col. 1, II. 14-24)...
>
> The device includes a sealing means (Fig. 2: elements 16), operating on the sleeve to prevent substantial leakage of gas from the body cavity on inflation when in an inoperative position and formed to mould to a substantial portion of a surgeon's hand or surgical instrument on insertion in an operating position (col. 4, II. 34-52)...
>
> In Fig. 3, the sealing means is provided by an inflatable first seal for engaging and retracting the incision (element 34: "outer wall") and a second inflatable seal (element 32: "inner wall") for sealing the lumen of the tube or sleeve bore (col. 4, II 28-36). (Emphasis added)

In the Yuen patent document there is no mention, implied or otherwise, of the described surgical retractor device being used in conjunction with an inflated (human) body cavity. The sealing means, Figure 2, element 16, is an inflatable cell element which constitutes the retractor device's body (cuff) and is not a seal against gas transfer from the internal human body to the exterior as interpreted by the examiner.

The Yuen reference (see column 4, lines 34-52) cited by the examiner does not support the argument made. Elements 34 and 32 of Figure 3, define the inner and outer surfaces of a common component, seal the device body itself and do not seal the lumen ends. These elements become more rigid upon inflation which enable the device to maintain an uncoiled state and therefore do not to seal the lumen ends. Acting in the capacity, element 34 will contact the incision and element 32 may contact an instrument placed within the bore but cannot form a seal against gas as inferred by the examiner since the element 32 is not stated anywhere in Yuen to be inflatable. See in particular Figure 5, where clearly shows that when the outer wall 34 is inflated the inner wall 32 is not inflated.

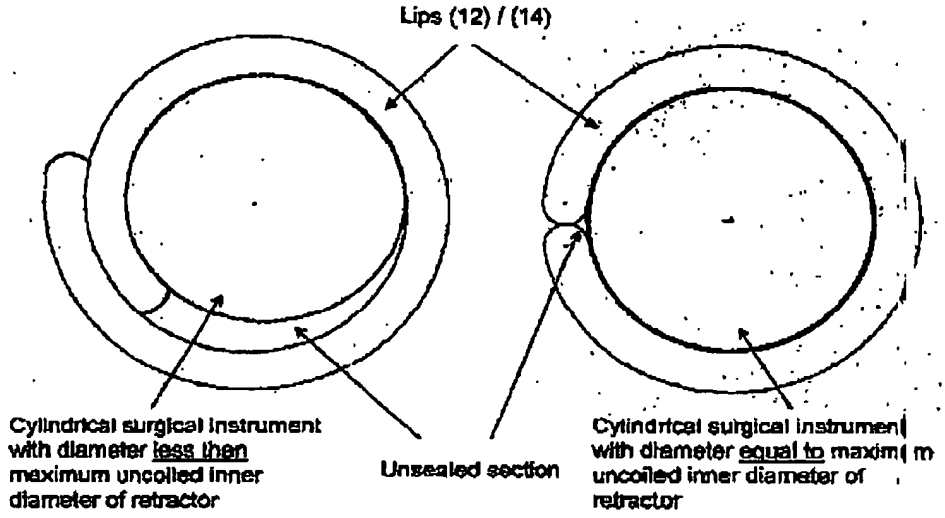
In the ***Response to Arguments*** portion of the Office Action, the Examiner has considered the Applicant's argument that "*Yuen does not prevent substantial leakage of gas from the body of the cavity*" but does consider it persuasive responding that:

> "If a surgical instrument is placed into the retractor as intended by Yuen, the device will substantially prevent leakage of gas from the body cavity. The device is constructed from a flexible plastic material. A device with this shape made out of flexible plastic would inherently conform the shape of a large object placed within it's center bore."

However, it is the Applicant contention that the device described by Yuen is solely for the purpose of holding the aperture of surgical incision open once the device has been inflated, thus uncoiling it and making it a rigid-walled structure with a central bore, open at both ends (see column 3, lines 48-54, and column 4, lines 17-30). This surgical retractor device does not provide the function of retaining pressurization of the inflated human body cavity during a pneumo-peritoneum procedure as gas or fluid from the human body interior to the exterior is not restricted.

While it is intended that the device is intended to be made from the thermoplastic, flexible, resilient material (see column 3, lines 55-57), it is not inevitable that the device would confirm to the shape of a large object placed within the bore. The design of the device, which includes the ring 30, means that the bore remains essentially circular regardless of extended diameter and therefore an interference fit can only be achieved with a cylindrical shape object. Furthermore,

the arrangement of the upper and lower lips (12 and 14) as illustrated in Figs. 1, 2 and 4 show that prevention of substantial gas leakage through the lumen of the device with a surgical instrument in situ is not necessarily achievable as there will always exist an unsealed portion around the instrument as shown below.



With regard to claim 3, the Examiner states that:

> Regarding claim 3, Yuen discloses in Fig. 2 a device in which the body cavity engagement means (14) is provided by a distal ring formed for insertion into the incision.

The element 14 described by the examiner as a "ring" is a lip, whose primary function is to connect the lowermost row of cuff pockets 16 (see column 3, lines 37-40) and to perform the secondary function (in conjunction with the upper lip 12) of helping to provide a uniform expansion or contracting up and down the longitudinal axis while the retractor is being used (see column 4, lines 30-33). While this lip is passed through the incision to reach the human body cavity, no reference is made to the lip acting as an engagement (seal) means.

With regard to claim 4, the examiner states that:

> Regarding claim 4, Yuen discloses in Fig. 2 a device in which the fixing means (12) is provided by a proximal ring for engaging with a patient's skin.

Yuen does not disclose the lip 12 as a skin engagement means but as a portion of the device where the inflation nozzle is located (see column 3, lines 23-26). A secondary function, in conjunction with lip 16, is described above. Fixation of the lip 12 to the skin is not taught anywhere in the disclosure of the device of Yuen.

With regard to claim 6, the Examiner states that:

> Regarding claim 6, Yuen discloses in Fig. 3 a device in which the first seal (34) is provided by an inflatable bladder extending outwardly from the sleeve on inflation to form a seal with the incision (col. 3, ll. 28-36). As the cuff is inflated, the outer wall (first seal) of the cuff becomes inflated expands, and forms a seal with the incision (col. 4, ll. 40-44).

However, element 34 is the outer wall off the cuff. No outwardly extending bladder is described anywhere in the patent document. Upon inflation the device uncoils and the outer wall contacts the incision, holding it open for surgical access. The sealing between the cuff and the incision as inferred by the examiner is not a requirement of the device of Yuen or its components and in practice mostly likely does not occur. Further, the reference section cited by the examiner, i.e., column 3, lines 28-36 and column 4, lines 40-44, respectively, are irrelevant and unsupportive of the arguments set forth by the Examiner.

That is, while the contact between the cuff and the incision may constitute a 'seal' by virtue of their proximity as stated by the Examiner in ***Response to Arguments***, see page 7, Figures 1 and 2 clearly illustrate that the design of the device wall and in particular the arrangement of the elements 16, means that gaps which create holes through the wall are present.

With regard to claim 7, the Examiner states that:

> Regarding claim 7, Yuen discloses in Fig. 3 a device in which the second seal (32) is provided by an inflatable bladder extending inwardly from the sleeve on inflation that is capable of preventing excessive loss of gas through the access port (col. 3, ll. 28-36). When the cuff is inflated, the inner wall (second seal) expands and is capable of being inflated to prevent loss of gas through the access port 9 (col. 4, ll. 40-44).

However, in the Yuen patent, ambiguity exists since inner wall element 32 is

described in one instance as a channel tube means connecting the inflatable cells 16 (see column 3, lines 30-31, and Figure 2) and in another instance as the inner wall of the cuff sleeve portion of the device (see column 4, lines 11-12 and Figure 3). In the former case it cannot be considered as an inflatable seal against loss of gas through the access port; while in the latter case element 32 is the reverse side of the component 34 and is not intended to prevent gas loss through the access port and is not inflated to form an inwardly extending bladder (see Figure 5). Indeed, given the argument outlined above for claim 6, whereby the sleeve contains holes it cannot perform this function.

> **With regard to claim 8,** the Examiner states that:
> Regarding claim 8,, Yuen discloses in Fig. 2 a device in which the second seal (32) is operatively connected and mounted within the first seal (34).

If this is the case then the Examiner is considering inner wall element 32 is a channel tube means connecting the inflatable cells as in Fig. 2, which is in contradiction to having used this evidence in the argument made regarding claim 7. If element 32 is taken to be a channel tube as the examiner has done in this instance, then it does not anticipate the seals whose function is taught and claimed.

Accordingly, since Yuen does not teach each and every feature of the claimed invention, the rejection of claims 1, 3, 4, and 6-8, under 35 U.S.C. §102(b), is not appropriate and must be withdrawn.

In order to clarify the issues for appeal, if the Examiner is to maintain the rejection of claims 1, 3, 4, and 6-8 under § 102(b) over Yuen then it is respectfully requested that the Examiner point out where in the teachings of Yuen it is explicitly stated or implicitly shown to be necessarily present (see MPEP Chapter 2112) that the element 32 is inflatable and where it is taught that the inner wall forms a seal.

Specifically, with regard to the rejection of claims 1, 3-8, under §102(b), as being anticipated by Williamson IV, the Applicants again note that the surgical device of claim 1 sets forth the following features:

... having:

distal body cavity engagement means (5) for insertion into the inci[illegible]sion to locate the device in position;

proximal fixing means (6) for attaching the device to a patient's sk[illegible]n;

a sleeve (4) connected between the body cavity engagement means (5) and the fixing means defining an access port; and

characterized in that the device includes sealing means (10, 12), op[illegible]erating on the sleeve (4) to prevent substantial leakage of gas from th[illegible] body cavity (2) on inflation when in an inoperative position and for[illegible]ned to mould to a substantial portion of a surgeon's hand or surgical ins[illegible]ument on insertion in an operating position, the sealing means being provi[illegible]ded by an inflatable first seal (10) for engaging and retracting the incisio[illegible] and a second inflatable seal (12) for sealing the lumen of the tube or sleeve bore. (Emphasis added)

In response to the highlighted features above, the Examiner's Office [illegible]ction states that:

> Regarding claim 1, Williamson, IV discloses...The device has a d[illegible]stal body cavity engagement means (Fig. 5. element 40) for insertion [illegible]nto the incision to locate the device in position, a proximal fixing m[illegible]ans for attaching the device to a patient's skin (Fig. 5: element 27)...[illegible]The device includes a sealing means (Fig. 5. elements 35 and [illegible]4), operating on the sleeve to prevent substantial leakage of gas from[illegible] the body cavity on inflation when in an inoperative position and form[illegible]d to mould a substantial portion of a surgeon's hand or surgical instru[illegible]ent on insertion in an operating position...

However, any person of ordinary skill in the prior art viewing Figures [illegible]0 and 11 of Williamson would clearly understand that 27 is an end cap and does n[illegible]ot make any contact with the patients skin. Again, as mentioned above, in order for [illegible] teaching to be inherent (as the Examiner is currently asserting since the sealin[illegible] function is nowhere stated or illustrated by the patentee), one of ordinary skill in [illegible]he art must appreciate that the "sealing" is necessarily present; however, the purpo[illegible]: of end cap 27 as a rigid end cap is stated (see column 4, line 20). This is even mor[illegible] evident that the end cap is not a seal to the patients skin since the inflation tube [illegible]5 would be located between the patients skin and the rigid end cap 27 which woul[illegible] preclude a sealing arrangement as presently claimed.

With regard to claim 3, the Examiner states that:

> Regarding claim 3, Williamson, IV discloses in Fig. 5 a device in [illegible]which the body cavity engagement means (40) is provided by a dist[illegible] ring

> formed for insertion into the incision. The distal end, 35 and 37 of 34, forms a ring share and is used for insertion. In Fig, 1, the engagement means (element 23 in this Figure) is shown inserted into the incision.

However, Figure 10 indicates that elements 35 and 37 do not engage the body cavity directly. Figures 6 and 10 show that engagement is via elements 39 and 33 which press against the inner surface of the body wall to secure the assembly in position (see column 6, lines 1-3). Further, the distal ring component recited in claim 3 is entirely distinctive from the ring shape formed by elements 35 and 37 in Williamson, IV as described by the Examiner.

> **With regard to claim 4,** the Examiner states that:
> Regarding claim 4, Williamson, IV discloses in Fig. 5 a device in which the fixing means is provided by a proximal ring (27) for engaging with patient's skin.

However, as discussed above element 27 is an end cap and clearly does not contact the body at any point. Its function is entirely different as described in column 3, lines 7-23 of Williamson, IV. Specifically, element 33, contacts the skin and is described as an 'annular rim' (see column 4, line 29) or alternatively as a rigid flange that sits adjacent the body wall (see column 5 ,lines 53-55).

> **With regard to claim 5,** the Examiner states that:
> Regarding claim *5,* Williamson, IV discloses in Fig. 5 a device in which the proximal ring (27) has an associated connector ring (25) for receiving additional seals or medical instruments".

However, Figure 5 clearly shows that 27 is an end cap as discussed previously and 25 a rigid base. At no point in the document is any reference made to the attachment or reception of additional seals or medical instrumentation.

> **With regard to claim 6,** the Examiner states that:
> Regarding claim 6, Williamson, 1V discloses in Fig. 5 a device in which the first seal (35) is provided by an inflatable bladder extending outwardly from the sleeve on inflation to form a seal with the incision (col. 5, II. 58-67); col. 6, II. 1-3). The outer inflatable sleeve 35, comprises of element 40, which is inflated and seals the incision.

However, the balloon/sleeve (40/35/39) acts as a single unit and presses against the inner wall surface of the body cavity. The incision is sealed by 39 while 40 holds the device in position. The presently claimed sleeve is a separate and distinct rigid

component with two seals attached, one extending inwardly and the other outwardly. The 'sleeve' described in the Williamson IV patent is a description of one function of the balloon and is not a sleeve in the same manner as presently claimed.

With regard to claim 8, the Examiner states that:

> Regarding claim 8, Williamson, IV discloses in Fig. 5 a device in which the second seal (34) is operatively connected and mounted within the first seal (35).

However, these seals are not separate components as presently claimed but are functional portion of a unitary balloon, which functions like a sphincter, i.e., they are two sides of a single component.

Accordingly, since Williamson IV does not teach each and every feature of the claimed invention, the rejection of claims 1, 3-8, under 35 U.S.C. §102(b), is not appropriate and must be withdrawn.

Specifically, with regard to the rejection of claims 1, 3, 4, and 6-8, under §102(b), as being anticipated by Mollenauer et al., the Applicants again note that the surgical device of claim 1 sets forth the following features:

> ... having:
>
> distal body cavity engagement means (5) for insertion into the incision to locate the device in position;
>
> proximal fixing means (6) for attaching the device to a patient's skin;
>
> a sleeve (4) connected between the body cavity engagement means (5) and the fixing means defining an access port; and
>
> characterized in that the device includes sealing means (10, 12), operating on the sleeve (4) to prevent substantial leakage of gas from the body cavity (2) on inflation when in an inoperative position and formed to mould to a substantial portion of a surgeon's hand or surgical instrument on insertion in an operating position, the sealing means being provided by an inflatable first seal (10) for engaging and retracting the incision and a second inflatable seal (12) for sealing the lumen of the tube or sleeve bore. (Emphasis added)

The Applicants again emphasize that with respect Mollenauer et al. it should be noted that independent claim 1 of the present application specifically requires that the sealing means operate on the sleeve. Mollenauer et al. nowhere suggests a sealing means which operates on the sleeve nor is such a sealing implicit in any of the

embodiments disclosed. If the outer layer of the balloons disclosed in Mollenauer et al. correspond to the inflatable first seal recited in claim 1 while the inner layer of the balloon corresponds to the second inflatable seal recited in claim 1, then there are no other elements in Mollenauer et al. to form the sleeve, note stiffener 48 has the walls of the inflatable envelope moving away from the stiffener 48.

That is, independent claim 1 specifically recites a sleeve and then separately recites a sealing means which includes two seals. Simply put, the Mollenauer et al. reference fails to disclose a sealing means operating on a sleeve and if the balloon structure of these prior art references are viewed as the inner and outer seal, then the prior art references fail to suggest a sleeve which is operated on by a sealing means. Finally, interpreting the balloon of Mollenauer et al. to include the structure and function of essentially most if not all elements of independent claim 1 is therefore inconsistent with the specific language of claim 1.

> **With regard to claim 3,** the Examiner states that:
> Regarding claim 3, Mollenauer et al. disclose in Fig. 17 a device in which the body cavity engagement means is provided by a distal ring (61) formed for insertion into the incision. In Fig. 12, the distal end of the balloon is formed by the outer balloon membrane, 50, and the inner balloon membrane, 49, which both create a ring shape that is inserted into the incision (col. 10, ll. 26-30)

Similarly to the Williamson IV device, the distal ring component recited in claim 3 of the present application is entirely distinctive from the ring shape formed by 50 and 49 which are the bulbous ends of the dumbbell shaped balloon in Mollenauer et at which protrude into the body cavity.

> **With regard to claim 4,** the Examiner states that:
> Regarding claim '1, Mollenauer et al. disclose in Fig. 17 a device in which the fixing means (60) is provided by a proximal ring for engaging with a patient's skin. In Fig. 12, the proximal end of the balloon is formed by the outer balloon membrane, 50, and the inner balloon membrane, 49, which both create a ring shape that remains on the skin (col. 10, ll. 30-33).

While the same argument as set forth above for claim 3 applies to claim 4, it is further noted that the examiner does not address certain features of the claim. That is, in one embodiment of the Mollenauer et al. device, shown in Fig. 18, a proximal flange (62) is described as being attached to the central stiffener tube (see column 10, lines 52-53)

such that the distal balloon portion clamps the skin/fat tissue between itself and the flange (column 10, lines 58-60). This flange would appear to be the same as the proximal ring of the instant claimed. However, although only a proximal flange is set forth and no reference is made to a separate flange located at the top and bottom, connected by an inner rigid tube, with both flanges engaging the skin, as in the present claims.

Accordingly, since Mollenauer et al. do not teach each and every feature of the claimed invention, the rejection of claims 1, 3, 4 and 6-8, under 35 U.S.C. §102(b), is not appropriate and must now be withdrawn.

While the present application is now believed to be in condition for allowance, should the Examiner find some issue to remain unresolved, or should any new issues arise, which could be eliminated through discussions with Applicants' representative, then the Examiner is invited to contact the undersigned by telephone in order that the further prosecution of this application can thereby be expedited.

Lastly, it is noted that a separate Extension of Time Petition (one month) accompanies this response along with an authorization to charge the requisite extension of time fee to Deposit Account No. 19-2380 (741890-19). However, should that petition become separated from this response, then this response should be construed as containing such a petition. Likewise, any overage or shortage in the required payment should be applied to Deposit Account No. 19-2380 (741890-19).

Respectfully submitted,

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